

**REMARKS**

The Applicants thank the Examiner for the thorough consideration given the present application. Claims 11-14 are pending. Claims 6-10 are canceled without prejudice to or disclaimer of the subject matter contained therein. Claims 11-14 are added, and claim 11 is independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

**Reasons for Entry of Amendments**

At the outset, it is respectfully requested that this Amendment be entered into the Official File in view of the fact that the amendments to the claims automatically place the application in condition for allowance.

In the alternative, if the Examiner does not agree that this application is in condition for allowance, it is respectfully requested that this Amendment be entered for the purpose of appeal. This Amendment reduces the issues on appeal by canceling claims 6-10, thereby reducing the number pending claims. This Amendment was not presented at an earlier date in view of the fact that Applicants did not fully appreciate the Examiner's position until the Final Office Action was reviewed.

**Acknowledgement of Information Disclosure Statement**

The Examiner has acknowledged the Information Disclosure Statement filed on July 25, 2002, but has **not** acknowledged the Information Disclosure Statement filed on January 30, 2002. Clarification is requested in the next official communications.

**Rejection Under 35 U.S.C. §103(a)**

Claims 1-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 96/34633 in view of Ebert et al. (U.S. 5,626,866). This rejection is respectfully traversed.

**Added Independent Claim 11, and Dependent Claims 12-14**

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the instant application, independent claim 11 is added herein to recite a combination of method steps in a method of preventing pressure-sensitive adhesive from leaking out in cold-flow during prolonged storage of a pressure-sensitive adhesive substrate section which is sealed in a bag in order to be protected against loss of active substance, said substrate section comprising:

a backing layer; and

a matrix connected to said backing layer, the matrix either being comprised entirely of a pressure sensitive adhesive material or provided with a pressure-sensitive adhesive layer on an application surface thereof;

said method comprising the steps of:

providing a carrier layer on a pressure-sensitive application surface of the matrix, the carrier layer being divided by an incision, and

configuring the carrier layer with two carrier layer sections, the two carrier layer sections projecting at least partially beyond said matrix, and overlapping each other in a region where they are joined.

The Examiner will note also that dependent claim 12-14 are added. These claims correspond to now-canceled dependent claims 7-10.

The Applicants respectfully submit that the combination of method steps set forth in independent claim 11, as added herein, is not disclosed or made obvious by the prior art of record, including WO '633, and Ebert et al.

In contrast to the presently claimed invention, WO '633 merely discloses a dressing set that keeps the active agent in a reservoir at a constant level for a prolonged storage time, and further discloses that the dressing set comprises a backing layer, a reservoir containing at least one pharmaceutically active substance, a pressure sensitive adhesive surface layer on one of the surfaces of the backing layer, and more than one pool strip which extend beyond the edges of the dressing. Thus, it can not be clearly and unambiguously inferred or made obvious from WO '633 Figure 2 that the peel strips 6 would indeed overlap if they would be tightly put against the foil and reservoir.

In addition Ebert et al. (U.S. '866) merely teaches a transdermal therapeutic drug delivery device in the form of a patch to deliver volatile drugs, wherein the peelable release liner is formed by two strips that overlap in the center, and the patch is sealed in a pouch.

However, neither of the cited references addresses or mentions the basic problem that is solved by the present invention, namely the leaking-out of pressure-sensitive adhesive from the pressure sensitive adhesive matrix or layer, which causes an undesired adhesion of the patch to the inside of the pouch or bag.

WO '633 indicates on page 2, second paragraph that dressing sets are known in which adhesion between the reservoir and/or backing and a barrier which is located in a pocket between a drug reservoir and a non-occlusive backing occurs. Pursuant to WO '633 this drawback is solved by placing a foil having an area being larger or at least equal to the area of the reservoir between said reservoir and said backing layer, wherein the foil is made of at least one hydrophilic or hydrophilized polymer and is in a moisture free state substantially occlusive and after absorption of moisture substantially non-occlusive (page 2, third paragraph). The adhesion between the reservoir and/or backing and a barrier is not a consequence of cold-flow of a pressure sensitive adhesive, and the barrier according to WO '633 is not the bag or pouch in which the patch is sealed. Furthermore, WO '633 does not point to the peel strip as means for preventing leaking-out of pressure-sensitive adhesive or preventing adhesion of the patch itself to any kind of support prior to its application.

Furthermore, Ebert et al. (U.S. '866) fails to teach or suggest that the peelable release liner may be utilized to prevent leaking-out of pressure-sensitive adhesive or to prevent adhesion of the patch itself to any kind of support prior to its application.

For the above-stated reasons, the Applicants respectfully submit that no combination of WO '633 or US '866 would teach or suggest the presently claimed method to the skilled artisan, in particular, because neither of these references relates to or mentions cold-flow or leaking-out of a pressure sensitive adhesive, nor do they indicate that the release line/peel strip may prevent adhesion of a patch to a support by the leaked-out adhesive. Each of the references cited by the Examiner concerns a solution to problems different from the problem addressed by the inventors of the presently claimed invention.

In view of the above amendments and arguments, independent claim 11, and claims 12-14 depending therefrom, are in condition for allowance.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) are respectfully requested.

### **CONCLUSION**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

*Application No. 09/980,211*  
*Amendment dated January 29, 2004*  
*Reply to Office Action of October 31, 2003*

*Docket No. :3868-0103P*  
*Art Unit: 1615*  
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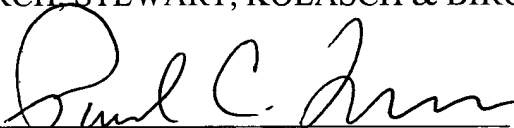
If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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